

Remarks:

Claims 13-20, 22-34, 46-49, 60-62, and 67-74 are pending in the application. In response to the Office Action, the applicants offer the following remarks directed to the claims in the order presented.

Rejections under 35 U.S.C. §102

Claims 46-49, 60-61, and 71-74 are rejected under 35 U.S.C. §102(b) as anticipated by Antenucci et al. The rejection is respectfully traversed, since Antenucci does not teach all of the elements of claims 46-49, 60-61, and 71-74. A *prima facie* case of anticipation has therefore not been presented. Specifically, all of these claims recite a precise numerical limitation regarding purity, and Antenucci provides no numerical teaching regarding purity level. Thus the rejections should be withdrawn.

The Applicants also note that Antenucci does not even suggest the desirability of making a product having the high purity levels recited in claims 46-49, 60-61, and 71-74, and thus would not provide motivation to seek such high purity. In fact, the Applicants are not aware of any such prior art teaching, and believe that such lack of teaching is due to the fact that, under prior art purification methods, a considerable yield loss would be expected if an effort were made to achieve such high purity levels. Such an expectation is borne out by the results cited in Fig. 1 of the application, as is discussed below in response to the Rejections under 35 U.S.C. §103. Thus a rejection under 35 U.S.C. §103 based on Antenucci would also be improper.

Rejections under 35 U.S.C. §103

Claims 13-20, 22-34, 62, and 67-70 are rejected under 35 U.S.C. §103(a) as unpatentable over Navia et al in combination with Catani et al. The Applicants respectfully traverse this rejection, in view of the amendments to the claims and the arguments provided herewith.

With reference to claims 13-20, 62, and 67-70, the Office Action states that Navia at col. 10 lines 9-31 teaches steam stripping of crude sucralose prior to crystallization, but this is not taught to, nor in fact does it, achieve removal of related chlorinated carbohydrates as

recited in amended claim 13. Neither is the subsequent extraction with an appropriate solvent taught by Navia to remove related chlorinated carbohydrates, and in fact the skilled artisan will recognize the steps taught at lines 9-31 as simple workup steps for separating the entire reaction product (including related chlorinated carbohydrates) from inorganic salts and residual DMF by extraction into a suitable solvent from which crystallization could subsequently be performed either directly (lines 26-28) or after transfer into water (lines 21-25). In neither case is there provided an increased purity sucralose solution containing a lower amount of the related chlorinated carbohydrates relative to sucralose, as recited in amended claim 13. Nor is there even a recognition in Navia of the desirability of purifying the sucralose in this way prior to the first crystallization.

The Office Action cites the Catani reference at col. 6 lines 43-45 as evidence of a teaching of the use of adsorbent technology as a yield-enhancing adjunct to crystallization or derivatization approaches, but the embodiments recited there (relating to Figs. C-E) give no indication of the desirability of using the adsorbent technology (or other pre-crystallization purification step) to remove related chlorinated carbohydrates prior to performing at least four crystallizations, with recycling of the mother liquor from at least one of these to the feedstock prior to the pre-crystallization purification step. Neither reference teaches or suggests four recrystallizations, and thus a *prima facie* case of obviousness has not been presented. Further, as discussed above in reference to Fig. 1, a combination of the pre-purification, multiple crystallizations, and recycle of mother liquor makes it possible to obtain the high purities and yields provided by this invention. Discussion of this point follows.

Referring to line 28 of FIG. 1 in the application, it is seen that in a prior art process, i.e. one without a non-crystallization purification step to remove related chlorinated carbohydrates, the use of repeated (three) crystallizations to achieve high (99.99%) impurity removal resulted in a very poor (9%) yield of sucralose, whereas the yield was nearly twice that (17%, but with only 98.90% impurity removal) after only one crystallization. However, when non-crystallization purification steps sufficient to remove ("purge") 50% or 75% of related chlorinated carbohydrates were performed prior to the first crystallization (see line 3 of Fig. 1), equal or higher yields (17% and 25%, respectively) were obtained compared with a single crystallization with no such pre-purification, while providing much higher (99.99%) impurity removal. The term "impurity" as used in the context of Fig. 1 means related chlorinated carbohydrates, as is made clear in paragraph [0005], and the Overall Impurity Removal figures

on line 48 of Fig. 1 reflect this meaning. The process of Fig. 1 is described in the specification beginning at paragraph [0061], and especially at [0072] and [0073].

The Applicants note that the increased yield of high purity product as seen on line 28 of Fig. 1 with repeated crystallizations, while simultaneously providing an extraordinarily pure sucralose, is counterintuitive; repeated crystallizations are typically expected to result in yield loss, but the present invention shows that this can be avoided by the combination of a pre-crystallization purification step and recycle of mother liquor to the feed for this step. Nothing in Catani or Navia, either alone or in combination, provides a motivation to make such a combination, nor does either reference suggest the desirability of using as many as four or more recrystallizations. Thus the rejection has been overcome by the amendment to claim 13, and this claim and its dependents (14-17 and 19-20) should be allowed. Claim 18 is cancelled herewith. Claim 62 is amended herewith to depend it from claim 13, and thus claim 62 and its dependents (67-70) should also be allowed.

The Office Action provides no arguments regarding claims 22-34, and thus has not presented a *prima facie* case of obviousness against these claims. Thus the rejection of claims 22-34 should be withdrawn. Nonetheless, claim 22 has been amended to incorporate the matter of dependent claim 23, which is canceled herewith. The Applicants would like to point out that any potential argument asserting obvious of these claims over Navia in combination with Catani, based on the arguments provided in the Office Action regarding claims 13-20, 62, and 67-70 as responded to above, should likewise be overcome by the amendments filed herewith, and thus these claims should be allowed as well.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response.

Respectfully submitted,



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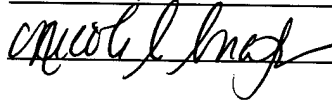
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